DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until January 21, 2004, the effective date for requiring establishments that engage in the recovery, screening, testing, processing, storage, or distribution of all human cells, tissues, and cellular and tissue-based products (HCT/Ps) not currently regulated under section 361 of the Public Health Service Act (PHS Act) and part 1270 (21 CFR part 1270) to register with FDA and list their HCT/Ps. FDA is taking this action to help ensure that the effective date for this rule is closer to the effective date of the anticipated finalization of the remaining proposed rules involving HCT/Ps.

DATES: The effective date for 21 CFR 207.20(f), 807.20(d), and 1271.3(d)(2) that published in the **Federal Register** on January 19, 2001 (66 FR 5447) is delayed from January 21, 2003, to a new effective date of January 21, 2004.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

We, FDA, are putting in place a new comprehensive approach to the regulation of HCT/Ps. The goal of the new approach is to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products. The new comprehensive approach to the regulation of different types of HCT/Ps is intended to be commensurate with the public health risks presented, enabling us to use our resources more effectively, increase consistency, and improve efficiency.

Since 1997, when we announced our comprehensive regulatory approach for HCT/Ps, we have published three proposed rules and finalized one of them:

- *The registration proposed rule*: ''Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products (63 FR 26744, May 14, 1998);

- *The registration final rule*: ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing'' (66 FR 5447, January 19, 2001);

- *The donor-suitability proposed rule*: ''Suitability Determination for Donors of Human Cellular and Tissue-Based Products'' (64 FR 52696, September 30, 1999); and

- *The GTP (good tissue practices) proposed rule*: ''Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement'' (66 FR 1508, January 8, 2000).

When the donor-suitability and the GTP proposed rules are finalized, the implementation of the comprehensive regulatory approach for HCT/Ps will be complete.

In all three proposed rules, we used the term ''human cellular and tissue-based products.'' In the registration final rule, we changed this term to ''human cells, tissues, and cellular and tissue-based products'' (HCT/Ps) in response to public comment. This change in terminology is a clarification and does not affect the scope of the definition in 21 CFR 1271.3(d), which continues to encompass an array of articles containing or consisting of human cells or tissues, and intended for implantation, transplantation, infusion, or transfer into human recipients, including investigational products. In the final rule, HCT/P is defined to include HCT/Ps at all stages of manufacture, from recovery through distribution.

Initially, we had intended to finalize and implement the registration proposed rule at the same time we finalized and implemented the two other HCT/P rules that would make up part 1271 (21 CFR part 1271) in its entirety. However, we issued the registration final rule, before finalizing the two remaining portions of part 1271 because of concerns raised about the safety of human tissue, which led us to believe that accelerating the collection of basic information about the rapidly growing tissue industry was vital. Because the registration final rule was published before the other two final rules, we decided to implement staggered effective dates so that certain HCT/Ps would fall within the scope of the new rule later when GTP requirements and enforcement provisions are finalized. This would ensure that certain products, such as heart valves and dura mater that are currently regulated as devices, would not be unintentionally and prematurely shifted into an incomplete regulatory scheme. Therefore, in the final registration rule, we required registration and listing first by those establishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissue

intended for transplantation currently regulated under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1270. Establishments that manufactured HCT/Ps described in § 1271.3(d)(1) were required to register within 30 days after the effective date of the registration final rule, i.e., May 4, 2001. Establishments that manufacture all other HCT/Ps, as described in § 1271.3(d)(2), were required to register 2 years after publication of the registration final rule, by January 21, 2003.

The registration final rule also established §§ 207.20(f) and 807.20(d) (21 CFR 207.20(f) and 807.20(d)), which required establishments that manufacture HCT/Ps regulated as drugs, biological products, and devices to register and list their products following the procedures in part 1271 instead of the procedures in 21 CFR parts 207 and 807. The effective date of §§ 207.20(f) and 807.20(d) is also staggered until January 21, 2003, because §§ 207.20(f) and 807.20(d) is not applicable until § 1271.3(d)(2) becomes effective. We expected to have finalized the donor suitability and the GTP proposed rules by this date. However, we will not complete the rulemaking process for the proposed donor suitability and GTP rules by January 21, 2003.

II. Reason for Staggered Effective Dates

Staggering the effective dates of this regulation permitted us to begin collecting important registration and listing information from those establishments currently regulated under part 1270, while continuing to proceed through rulemaking to develop the remainder of part 1271. We believed that this action would prevent an unintentional gap in the regulation of certain currently regulated HCT/Ps, permit an orderly implementation process, and avoid duplicative information collection. If we instead implemented the registration final rule for all HCT/Ps at the same time, certain

HCT/Ps, such as heart valves and dura mater that are currently regulated as devices, would no longer be regulated as devices but rather would shift into the regulatory scheme under part 1271. By implementing a staggered effective date for such products, we avoided a premature shift that essentially would have left these products unregulated until the donor suitability and GTP rulemaking process is completed. FDA also staggered the effective dates of the registration final rule to ensure the orderly implementation of the HCT/P regulations.

III. Need for Further Delay of Effective Date

In the registration final rule, we stated that unanticipated delays in completing the rulemaking for the remainder of part 1271 could occur, and if so, we would consider whether to extend the staggered effective date for some or all of the affected HCT/Ps. Due to the numerous comments submitted to FDA regarding the proposed donor suitability and GTP rules, we will not be able to finalize these rules by January 21, 2003. We have concluded that implementing the registration final rule under the staggered effective date for the remaining HCT/Ps would be contrary to the public interest in that certain products would become unregulated unless and until the GTP and donor suitability rules are finalized. For HCT/Ps subject to the staggered effective date, requiring registration without adequate enforcement provisions, such as those proposed in the GTP rule, would be premature and possibly ineffective. Establishments that manufacture HCT/Ps covered by the staggered effective date have been registering voluntarily, and FDA is willing to continue accepting such voluntary registrations.

FDA, for good cause based on the reasons stated previously, finds that notice and public procedure to delay the effective date are unnecessary and

contrary to the public interest (5 U.S.C. 553(b)(3)(B)). Therefore, we are delaying the effective date of §§ 207.20(f), 807.20(d), and 1271.3(d)(2) for 1 year. The new effective date is January 21, 2004.

Dated: January 8, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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